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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD E. PARIZEK, LONNY E. VLIEGER, SHARON A. BRYANT, STUART K. NIBBELINK, and MICHAEL J. MCGINLEY

Appeal 2009-007089
Application 10/748,524
Technology Center 1600

Decided: November 18, 2009

Before TONI R. SCHEINER, DEMETRA J. MILLS, and ERIC GRIMES, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of immunizing cattle. The Examiner has rejected the claims as obvious and lacking adequate written description in the Specification. We have jurisdiction under 35 U.S.C. § 6(b). We affirm the obviousness rejection but reverse the rejection for lack of adequate written description.

STATEMENT OF THE CASE

The Specification discloses that multicomponent vaccines made from whole cultures of organisms contain numerous antigens: "Some of these are protective antigens.... Some of these antigens are detrimental to protection of the animals or cause reaction in the animals." (Spec. 1: 21-24.)

Claims 46-48 are pending and on appeal. Claim 46 is representative and reads as follows:

> 46. A method of immunizing cattle without significant injection site lesion formation, comprising injecting into said cattle about 2 ml of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from six clostridial organisms, a protective antigen component from at least one nonclostridial organism, which is Moraxella Bovis (M. Bovis), and an encapsulating polymer adjuvant, whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection and whereby injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished.

Claims 46-48 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description in Specification; and under 35 U.S.C. § 103(a) as being obvious in view of Roberts[1] and Lund.[2]

WRITTEN DESCRIPTION

The Examiner has rejected claims 46-48 under 35 U.S.C. § 112, first paragraph, on the basis that the Specification does not provide support for the reduction of injection site lesion formation by at least 41% with a 2 ml vaccine injection compared to a 5 ml vaccine injection (Ans. 8). The

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[1] Roberts, WO 94/22476, Oct. 13, 1994
[2] Lund, US 3,920,811, Nov. 18, 1975

Examiner finds that the Specification's Table 12 shows "the reduction of lesions after weaning is only 33.2%" (*id.* at 9).

Appellants argue that the Specification's Table 12 shows that "the reduction in the number of lesions from the 5 ml dose when using the 2 ml dose is from 79.5% of the cattle to 46.3% of the cattle, a reduction of 41% in the number of cattle having lesions" (Appeal Br. 14).

We agree with Appellants' interpretation of the evidence. Table 12 of the Specification shows that cattle immunized with a 2 ml vaccine had an incidence of lesions at weaning of 46.3%, compared to 79.5% for cattle immunized with a 5 ml vaccine (Spec. 54: 1-10). This reduction in incidence of lesions is at least a 41% reduction: (79.5 - 46.3)/79.5 x 100 = 41.76%.

We therefore find that the Specification provides an adequate written description for the "at least 41%" limitation. The rejection of claims 46-48 under 35 U.S.C. § 112, first paragraph, is reversed.

OBVIOUSNESS

Issue

The Examiner has rejected claims 46-48 under 35 U.S.C. § 103(a) as being obvious in view of Roberts and Lund. Claims 47 and 48 have not been argued separately and therefore stand or fall with claim 46. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner finds that "Roberts teaches methods of preventing or treating a clostridial infection in a bovine animal" by administering a vaccine comprising components from six different Clostridium species, antigens from *Moraxella bovis*, and a dispersible soluble adjuvant (Ans. 5).

The Examiner also finds that Roberts teaches vaccine doses of between 1-5 ml (*id.*).

The Examiner finds that "Roberts discloses the prior art as teaching [that] other potent adjuvants, including CARBOPOL™ polymers have been used with clostridial vaccines" (*id.* at 5-6) and that "Lund teaches [that] an adjuvant polymer, such as CARBOPOL™, is retained at the site for prolonged slow release that acts by adsorbing the active agent onto the polymer" (*id.* at 6). The Examiner concludes that it would have been prima facie obvious to use Lund's encapsulating polymer adjuvant in Roberts' method of immunizing cattle (*id.* at 7).

Appellants contend that the Examiner erred in finding that one of skill in the art would have been motivated to combine Lund's polymeric (depot) adjuvant with Roberts' vaccine because Roberts "teaches against using an encapsulating polymer adjuvant that releases antigens slowly at the site of injection" (Appeal Br. 11). Appellants also contend that the cited reference do not suggest administering the composition in a 2 ml dose (*id.* at 13).

The issues with respect to this rejection are: Does the evidence of record support the Examiner's conclusions that (i) one of skill in the art would have been motivated to combine Lund's encapsulating adjuvant with Roberts' clostridial vaccine and (ii) that the cited references suggest a 2 ml dose?

Additional Findings of Fact

1. Roberts discloses that clostridial infections "are generally controlled prophylactically, using vaccine compositions containing one or more clostridial bacterins or toxoids" (Roberts 1: 27-29).

2. Roberts discloses that "clostridial vaccines require adjuvants in order to increase antigenic potency and enhance stability" (*id.* at 1: 33-35).

3. Roberts discloses that "potent depot adjuvants, such as water-in-oil emulsions and carbopol, have also been used in clostridial vaccines. The above-described adjuvants, although increasing antigenicity, usually provoke severe persistent local reactions, such as granulomas, abscesses and scarring, when injected subcutaneously or intramuscularly" (*id.* at 2: 1-4).

4. Roberts discloses that "the water-soluble adjuvant, saponin, can be used in place of a depot adjuvant in multicomponent clostridial vaccines for cattle" (*id.* at 2: 22-24)

5. Roberts discloses a "multicomponent clostridial vaccine composition comprising: (a) clostridial bacterins or toxoids derived from each of *Clostridium haemolyticum*, *Clostridium chauvoei*, *Clostridium septicum*, *Clostridium novyi*, *Clostridium sordellii*, *Clostridium perfringens*, Type C and *Clostridium perfringens*, Type D; and (b) a saponin adjuvant" (*id.* at 2: 35 to 3: 5).

6. Roberts discloses that "[n]on-clostridial antigens may also be added to the vaccines to afford protection against a wide spectrum of diseases. For example, antigens derived from *Moraxella bovis*, … can be added" (*id.* at 5: 11-14).

7. Roberts discloses that "to immunize cattle with the clostridial vaccine compositions described above, generally between 0.5 ml to 10 ml will be administered, more preferably 1 to 5 ml. Other effective dosages can be readily established by one of ordinary skill in the art through routine trials" (*id.* at 8: 30-33).

8. Lund discloses that the "use of a polymer of acrylic acid cross-linked with various polyol compounds as an adjuvant is described in [the prior art]. Such polymers are commercially available under the trademark 'Carbopol.'" (Lund, col. 1, ll. 50-53).

9. Lund discloses that "Carbopol behaves in a manner similar to other gels such as collagen and aluminum hydroxide; namely, the active agent is adsorbed on the polymer and the combination is retained at the injection site. The polymer is only slowly dispersed and the active agent is retained at the site for prolonged slow release." (*Id.* at col. 1, l. 67 – col. 2, l. 5.)

10. Lund discloses that "Carbopol-934 is the acrylic acid polymer cross-linked with approximately 1% polyallylsucrose" (*id.* at col. 3, ll. 47-49).

11. Lund discloses "injectable mixtures of a substantially neutralized polymer of acrylic acid cross-linked with from 0.75 to 2.00% of polyallylsucrose or polyallylpentaerythritol and an amount of a physiologically acceptable electrolyte effective to lower substantially the viscosity of aqueous solutions of the adjuvants" (*id.* at col. 2, ll. 53-58).

Principles of Law

The obviousness analysis "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). "[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness." *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004).

"[I]n a section 103 inquiry, 'the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.'" *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989).

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant.

In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994).

"[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art." *In re Baxter-Travenol Labs.*, 952 F.2d 388, 392, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991).

Attorney argument is not evidence. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).

Analysis

Claim 46 is directed to a method of immunizing cattle by injecting them with about 2 ml of a vaccine comprising protective antigens from six clostridial organisms, a protective antigen component from *Moraxella bovis*, and an encapsulating polymer adjuvant that releases antigens slowly at the site of injection. Claim 46 also requires that injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of the vaccine.

Roberts discloses multicomponent clostridial vaccine compositions with components from six clostridial species, and suggests the addition of a protective antigen component form *Moraxella bovis* to the composition. Roberts also suggests vaccine doses of 1-5 ml. Both Roberts and Lund disclose the use of carbopol polymer adjuvants for use with clostridial vaccines, and Lund suggests that such adjuvants would provide the slow release of the antigenic components.

In view of these disclosures, it would have been obvious to one of skill in the art to immunize cattle with a multicomponent vaccine comprising a protective antigen component from six clostridial organisms, a protective antigen component from *M. bovis*, and a carbopol slow-releasing encapsulating polymer adjuvant. Such a combination is no more than the predictable use of prior art elements according to their established functions. Using a 2 ml vaccine dose would have been obvious because it is within the 1-5 ml dosage range suggested by Roberts.

Appellants contend that one of skill in the art would not have been motivated to combine a polymeric depot with Roberts' vaccine because Roberts "teaches against using an encapsulating polymer adjuvant that releases antigens slowly at the site of injection" (Appeal Br. 11).

This argument is not persuasive. While Roberts discloses that depot adjuvants can cause local reactions, it also discloses that carbopol is a potent adjuvant that has been used in clostridial vaccines. Both Roberts and Lund disclose that depot adjuvants were known to be effective adjuvants and Roberts discloses that clostridial vaccines require adjuvants. Thus, Roberts would not have suggested that using a carbopol as an adjuvant "is unlikely to

be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d at 553. Rather, Roberts would have led one of skill in the art to understand that, while carbopol has the potential to provoke local reactions, it is an effective adjuvant that was used in the art with clostridial vaccines.

Appellants also contend that the cited references do not suggest administering the composition in a 2 ml dose (Appeal Br. 13). Appellants argue that "the dosages taught [by Roberts] apply only to vaccines based on soluble adjuvants and not vaccines comprising depot adjuvants, such as Appellants' encapsulating polymer adjuvants" (*id.*).

This argument is not persuasive. Roberts discloses that an effective vaccine can be formulated in doses ranging from 0.5 ml to 10 ml, preferably, 1 ml to 5 ml, and that "effective dosages can be readily established by one of ordinary skill in the art through routine trials" (FF 7). Appellants have cited no evidence to support their position that, if Roberts' composition were modified to include a carbopol adjuvant, those skilled in the art would not have considered a dosage of 2 ml obvious.

Appellants also contend that they have overcome any prima facie case of obviousness with unexpected results; specifically, a 41% decrease in lesion formation in animals treated with a 2 ml dose of vaccine, compared to those treated with a 5 ml dose (Appeal Br. 11).

This argument is not persuasive. Unexpected results must be shown to be unexpected when compared to the closest prior art; here, the clostridial vaccine disclosed by Roberts. The Specification states that "a 2.0 mL dose 6-way multicomponent clostridial vaccine of the invention was less reactive in calves than a 5.0 mL dose conventional technology 6-way clostridial

product" (Spec. 55: 14-16). However, Appellants have not provided evidence that the "conventional technology" vaccine represents the closest prior art product, or that the results obtained for the claimed composition were unexpectedly superior. Attorney argument is not evidence.

Conclusion of Law

The evidence of record supports the Examiner's conclusions that (i) one of skill in the art would have been motivated to combine Lund's encapsulating adjuvant with Roberts' clostridial vaccine and (ii) that the cited references suggest a 2 ml dose.

SUMMARY

We reverse the rejection of claims 46-48 under 35 U.S.C. § 112, first paragraph, as lacking adequate written description in Specification. However, we affirm the rejection of claims 46-48 under 35 U.S.C. § 103(a) as being obvious in view of Roberts and Lund.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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